IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
	:	
v.	:	**CRIMINAL ACTION NO. 19-717**
	:	
	:	
WILLIAM A. MERLINO	:	

McHugh, J. **September 9, 2022**

MEMORANDUM

A jury has found Defendant William Merlino guilty of introducing misbranded drugs into interstate commerce with the intent to defraud in violation of 21 U.S.C. § 331. Merlino now renews his Motion for Judgment of Acquittal under Federal Rule of Criminal Procedure 29. ECF 79. Because I find that the Government presented sufficient evidence to support the guilty verdict rendered against him, Merlino's Motion will be denied.

I. Background

Merlino is a retired doctor who operated a business encapsulating, packaging, labeling, and distributing the chemical 2,4-Dinitrophenol ("DNP") for use as a human drug. DNP is an industrial chemical with commercial uses, including in agriculture. Indictment, ¶ 8, ECF 1. In the 1930's, prior to the passage of the Federal Food, Drug, and Cosmetic Act ("FDCA"), DNP was sold as a weight loss drug. *Id.* at ¶¶ 9-10. "DNP caused serious adverse events, including dehydration,

cataracts, liver damage, and death. As more side effects were reported, FDA determined that DNP was too toxic to be used for human consumption." Gov't Resp. at 2, ECF 80.

At trial, the Government introduced evidence that Merlino sold and distributed DNP to hundreds of people across the United States, Canada, and the United Kingdom.[1] In so doing, he used a variety of pretexts. For example, he tweeted, "DNP for sale on eBay for weight loss. Is not legal in US so listed as fertilizer on eBay. #Diet #weightloss." Gov't Ex. 1. After the United States Customs and Border Protection ("CBP") seized his bulk product, Merlino wrote a letter to CBP in an attempt to recover the product, stating, "DNP is used as an herbicide and for preserving wood. . . This product cannot be consider [sic] a drug as it is toxic to human." Gov't Ex. 5. Yet, he continued to encapsulate the drug and communicate with customers about dosage for human consumption, all while labeling his drugs "Not For Human Consumption" and describing DNP as fertilizer on his website. *See* Gov't Resp. at 3-4. Merlino also used a variety of return addresses for the parcels he shipped out. *Id.* at 4. Merlino now admits that "[v]arious other exhibits and testimony made clear that Dr. Merlion's [sic] customers were purchasing his DNP for human consumption." Mot. at 3.

The crux of his renewed motion is that he lacked the intent to defraud necessary to support a felony misbranding conviction.

II. Standard of Review

Rule 29 of the Federal Rules of Criminal Procedure provides that a court, "on the defendant's motion[,] must enter a judgment of acquittal of any offense for which the evidence is insufficient to sustain a conviction." Fed. R. Crim. P. 29(a). Because "we trust jurors to judge the evidence," courts review sufficiency of evidence under a "highly deferential" standard and "will

[1] Although the trial transcript is not yet available, the trial was recent and the details are fresh in the Court's mind.

overturn a verdict only if no reasonable juror could accept the evidence as sufficient to support the conclusion of the defendant's guilt beyond a reasonable doubt." *United States v. Caraballo-Rodriguez*, 726 F.3d 418, 430–31 (3d Cir. 2013). In its review, the court must view the entire record—not just isolated parts—"in the light most favorable to the prosecution." *Id.* (citation omitted). Under this standard, "[w]hile evidence proffered at trial may be consistent with multiple possibilities," the role of a reviewing court "is to uphold the jury verdict—and not to usurp the role of the jury—as long as it passes the 'bare rationality' test." *Id.* at 432.

III. Discussion

Merlino levies a two-pronged attack on his conviction. First, he argues that felony misbranding requires proof of an intent to deceive those who purchase a drug from the defendant, such that evidence showing only intent to deceive a government agency is insufficient to sustain a conviction. Alternatively, he argues that even if fraud on an agency suffices, there was no proof at trial that Merlino intended to deceive any government agency. I address each argument in turn.

a. Intent to defraud under § 333(a)(2) encompasses fraud on the FDA

Violations of 21 U.S.C. § 331 of the FDCA are strict liability misdemeanors unless the defendant "commits such a violation with the intent to defraud or mislead." § 333(a)(2). Then, the offense converts to a felony. *Id*. The statutory language contains no limiting definition as to who must be "defrauded" or "misled" to make a violation of the statute a felony. Merlino advances a narrow interpretation, arguing that the relevant intent is limited to ultimate consumers, and further contending that because "Dr. Merlino sold DNP to people who wanted it and knew what they were getting," his felony conviction cannot stand. Mot. at 1.

Although the Third Circuit has not ruled on this precise issue, the unanimous consensus among circuits is that § 333(a)(2) applies if the defendant intended to deceive either consumers or

regulatory agencies, or both. *See e.g., United States v. Dessart*, 823 F.3d 395, 403 (7th Cir. 2016); *United States v. Ellis*, 326 F.3d 550, 554 (4th Cir. 2003) ("The inquiry, therefore, is whether the defendant designed his conduct to avoid the regulatory scrutiny of the FDA."); *United States v. Milstein*, 401 F.3d 53, 69 (2d Cir. 2005)("[A] defendant may be convicted on evidence that government agencies were the subject of the intent to defraud."); *United States v. Arlen*, 947 F.2d 139, 143 (5th Cir. 1991) ("[T]he government's evidence is sufficient to make out a violation of this section where it shows that the defendant intentionally violated § 331 with the specific intent to defraud or mislead an identifiable government agency."); *United States v. Bradshaw*, 840 F.2d 871, 874 (11th Cir. 1988) cert. denied, 488 U.S. 924 (1988) ("[T]he structure of the statutory scheme, the purpose of the statute, and the case law persuade us that Congress meant to encompass conduct intended to defraud government enforcement agencies.").

I agree with the prevailing consensus. [2] First, the statutory language is broad, with no limitation specified. Congress could have explicitly limited the intent requirement to consumers but did not. Second, the structure of the statutory scheme indicates that "intent to defraud" encompasses fraud on government agencies. 21 U.S.C. § 331 lists the behavior that constitutes criminal violations of the Act. Several of these violations concern only conduct directed toward the government. *See* 21 U.S.C. § 331(e) (failure to permit FDA access to records and failure to make reports to the FDA); § 331(f) (refusal to permit FDA inspection); § 331(p) (failure to register with the FDA). As the court in *Bradshaw* reasoned, reading those sections with § 333 makes it

[2] Merlino disagrees that there is a "consensus" among circuits. Specifically, in Reply, Defendant argues that the "Government incorrectly claims that there is a 'consensus among the circuits' that the intent to deceive regulatory authorities establishes the 'intent to defraud or mislead' necessary to convict on felony-misbranding charges. A consensus means that everybody agrees. But the Third Circuit doesn't." This argument is based on an overly broad reading of *States v. Greenbaum*, 138 F.2d 437 (3d Cir. 1943), as discussed in greater detail later in this Memorandum.

clear that "the FDA is the entity most likely to be defrauded under these provisions." 840 F.2d at 874. Adopting Merlino's proposed reading would lead to the incongruous result that there could never be a felonious violation of §§ 331 (e), (f), or (p).[3] Logically, therefore, "intent to defraud or mislead" extends to government agencies.

To refute this conclusion, Merlino asserts without citation that "[m]isbranding is not about the defendant's interaction with the FDA. Instead, it is about consumer protection. . . Misbranding does not involve any interaction with the FDA." Mot. at 10. In response, the Government notes that there are many misbranding violations that depend on interactions with the FDA. *See* Resp. at 14 (citing 21 U.S.C. §§ 352 (ff),(y),(f)). Merlino's argument also ignores the fact that by frustrating the FDA's attempts to protect the public, he was simultaneously misleading and defrauding the public, albeit indirectly.

Finally, despite Defendant's arguments to the contrary, existing Third Circuit precedent does not require a different result. Defendant first cites *United States v. Greenbaum*, 138 F.2d 437 (3d Cir. 1943), for the proposition that where "[buyer] of the shipment knows what he is getting and what he wants," there can be no intent to defraud or mislead.[4] The issue in *Greenbaum* was whether *misdemeanor* misbranding requires knowledge or willfulness. In rejecting one of the government's arguments as to why there should not be a *mens rea* requirement for the

[3] In addition, Merlino also argues that the government should have instead charged him with "failure to register" under § 331(p). But the fact that the government could have chosen to bring "failure to register" charges under § 331(p) does not mandate a narrow reading. *Wayte v. United States*, 470 U.S. 598, 607 (1985) (noting that the decision as to which charges to file rests entirely in the prosecutor's discretion).

[4] In the same paragraph, Defendant also cites *United States v. Haga*, 821 F.2d 1036 (5th Cir. 1987), which questioned in *dicta* whether the government could establish a § 333(b) violation by showing that the defendant defrauded or misled a government agency. He overlooks the fact that, when squarely presented with the issue in a later case, *United States v. Arlen*, 947 F.2d 139, 142–43 (5th Cir. 1991), the Fifth Circuit held that "the government's proof of [the defendant's] intent to defraud a government agency could establish a violation of § 333(b)."

misdemeanor section of the statute, the court briefly discussed the felony misbranding section, musing that "there can be instances where the introduction of a prohibited article in interstate commerce is with knowledge and willfulness and yet without intent to deceive or mislead, e.g., where the consignee of the shipment knows what he is getting and gets what he wants." *Id*. Merlino seizes on this language to argue that here "the customers got what they wanted," which necessarily bars any inference of intent to defraud. Mot. at 3.

This argument fails. First, the portion that Merlino relies on is *dicta.* In Reply, Merlino argues that this analysis "was a necessary part of the Third Circuit's construction of § 333." Reply Br. at 2. I disagree. The evidence required to sustain a felony conviction was neither at issue nor substantively discussed in *Greenbaum*. Second, even if the language were read to preclude intent to defraud where a customer purchases a drug with full knowledge, the *Greenbaum* court was listing one example of a situation that might not satisfy the intent to defraud standard. Nothing in the passage cited addresses a case where a customer may have "got what they wanted," but a seller simultaneously intended to deceive the regulatory agency.

The Defendant's reliance on *United States v. Goldberg*, 538 F.3d 280, 289 (3d Cir. 2008), as amended (Nov. 6, 2008) is similarly misguided, because the facts of that case were far different. There, the Defendant openly discussed his operations with his customers and had called the FDA seeking approval for a novel theory he believed would make him exempt from prescription requirements. The FDA told him on multiple occasions that his belief was mistaken, and his activity was illegal. Based on a finding that Goldberg had "conducted his admittedly illegal ventures in the open, and (at least as far as the drugs that led to the misbranding counts with which he was charged) in accordance with all the agreements he made," the court vacated his felony misbranding convictions, rendering them misdemeanors instead. *Id*. at 290. In so doing, it noted

that "the record has not yielded any trace of an intent on Goldberg's part to avoid detection or misrepresent what he was up to." *Id*. at 291. Here, in contrast, the evidence showed that Merlino actively took many steps to avoid detection. As the Government points out, unlike the defendant in *Goldberg* who openly defied regulatory authorities because he thought he had found a legal justification for doing so, Merlino took pains to skirt regulatory scrutiny by labeling the product as something it was not and representing that it was not for human use when he fully intended it to be used as a drug. Moreover, the *Goldberg* court did not hold that the intent to defraud must be directed only at consumers but reviewed the record for evidence of intent to defraud both consumers and regulatory agencies.

In support of his position that the Third Circuit precedent requires a narrow interpretation of the statute, Merlino also cites two cases affirming convictions under 333(a)(2) that considered only interactions with customers. *See United States v. Bansal*, 663 F.3d 634 (3d Cir. 2011); *United States v. Abuarquob*, 294 F. App'x 722 (3d Cir. 2008) (non-precedential). This ignores an important distinction. While evidence of intent to defraud consumers is *sufficient* to sustain a conviction under 333(a)(2), it is not *necessary* for a conviction. The Third Circuit's focus on evidence of intent to defraud consumers in affirming those convictions was a function of the record in those cases; it provides no insight into whether intent to defraud an agency would also suffice.

b. There was evidence that Merlino intended to defraud the FDA or Customs

In the alternative, Merlino argues that even if proof of fraud on the FDA is sufficient to sustain a conviction for felony misbranding, the "Government presented no evidence that Dr. Merlino ever gave false information to the FDA," so his conviction must be overturned. Mot. at 3. This argument fails because the record reflects ample evidence from which a juror could conclude that Merlino intended to defraud the FDA and the CBP.

Defendant cites *United States v. Mitcheltree*, 940 F.2d 1329, 1348 (10th Cir. 1991) for the proposition that proof of a specific attempt to mislead the FDA, or a communication to the FDA that omits material information, is necessary to sustain a conviction. Mot. at 11. He goes on to argue that the evidence here falls short of that standard, as "[t]here were no communications between Dr. Merlino and the FDA. Dr. Merlino could not have somehow intended to defraud or mislead it." Mot. at 13.

I reject Merlino's expansive reading of *Mitcheltree*. The court there required "proof of an intent to mislead or defraud which is *connected to the misbranding violation under § 331*." 940 F.2d 1329 at 1350 (emphasis in original). Even if *Mitcheltree* were binding in this circuit, the conduct here meets that standard. For example, Merlino's tweet specifically connects the fact that DNP is not legal as a drug to the fact that it was being listed for sale as fertilizer. He also wrote a letter to CBP which continued his ruse to avoid detection.[5] In the letter, he directly interacted with an agency and falsely represented that his DNP was not used for human consumption, despite his clear understanding that his customers sought and obtained the DNP for weight loss. Merlino also used a variety of different return addresses and labeled his product "not for human consumption" to avoid scrutiny. In addition, the Government introduced emails from a customer identified as David, who explained that he wanted to promote Merlino's product, but it would be "SUPER safely done. . . [Merlino] would never have to worry about anything like someone doing something

[5] In Reply, Merlino argues that contents of "any statement to CBP are irrelevant" because *Mitcheltree* demands "a misstatement to a 'government agency involved in consumer protection' that regulates drugs—that is, 'the FDA or its state counterpart.'" Reply at 6 (quoting *Mitcheltree*, 940 F.2d at 1350, 1352). But the *Mitcheltree* court also acknowledged that a defendant may knowingly misbrand if there is intent to mislead a "government agency involved in consumer protection ***of some sort***." *Mitcheltree*, 940 F.2d at 1352 (emphasis added). Here, CBP's interdiction of the DNP as it entered the United States would fall within that definition, and the misrepresentations Merlino made in his attempt to recover the DNP were meant to disguise the fact that it would be consumed. Finally, even accepting the Defendant's reading of *Mitcheltree,* there was sufficient evidence at trial of Merlino's intent to defraud the FDA.

stupid or even talking about the product for human consumption." Gov't Resp. at 10. Merlino replied that he was "interested" and that the product would need to be shipped as "Yellow Pigment 12." *Id*. When agents searched his residence, they found bulk DNP, empty containers from the chemical supply company, capsules, labels, shipping supplies and pill/encapsulating presses. *Id.* There is ample evidence from which a reasonable juror could find intent to defraud and that Merlino was intentionally trying to evade the regulatory authority of the FDA and Customs.

c. There was also evidence of intent to defraud the consumer

Finally, even if fraud on consumers were required to support a felony misbranding conviction, the Government also introduced such evidence. For example, Merlino wrote an advertisement on eBay stating, "as a retired physician, I have used DNP for patients, when it was legal, and discovered that its mechanism of action worked on plants to slow growth." Gov't Ex. 2. But DNP has not been a legal drug in the United States since 1938, so it is chronologically impossible for Merlino ever to have legally provided DNP to patients. At least one customer, identified as J.K., emailed Merlino to ask him about how DNP "worked within the body back when it was a legal medication for humans and not just for plants." Gov't Ex. 12A. A reasonable juror could conclude from this evidence that he intended to deceive consumers.

IV. Conclusion

For the reasons set forth above, Defendant's Motion will be denied, and his conviction stands. An appropriate order follows.

s/Gerald Austin McHugh
United States District Judge